Serial No.: 10/632,008
Examiner: Sharon E. Kennedy
Group Art Unit: 1615

STATUS OF CLAIMS

Claims 1-27 are presently pending in the application. Claims 24-27 were previously withdrawn from consideration pursuant to a restriction requirement and are hereby cancelled. Claims 2 and 3 were previously cancelled. Thus, claims 1 and 4-23 are presently under examination. Applicants hereby amend claim 1. Support for the amendment to claim 1 is found, *inter alia*, in the claims as originally filed and in paragraphs [0020], [0021], and [0065] to [0070] of the specification. Applicant submits that no new matter has been added.

REMARKS

Rejection Under 35 U.S.C. §102(b) Under Zaffaroni et al.

Claims 1, 5, 6, and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zaffaroni et al. (U.S. Pat. No. 3,896,819). Specifically, the Examiner asserts that "Zaffaroni et al. discloses a silicone-carbonate copolymer in column 13, lines 29-30 which anticipates Applicants' claimed polymeric release region comprising a silicone copolymer."

In response, Applicants respectfully traverse the rejections and their accompanying remarks. Zaffaroni et al. does not teach the invention of the claims. Specifically, Zaffaroni et al. fails to teach all of the elements of the present invention as claimed in amended independent claim 1, which is directed to an implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric *carrier region that comprises said therapeutic agent and which releases said therapeutic agent* upon administration to a patient, said polymeric *carrier* region comprising a *silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units*.

For a reference to anticipate a claim it must disclose ***each and every element*** of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978)(emphasis added).

The Zaffaroni et al. reference fails as an anticipatory reference because it fails to disclose all of the features of the claimed invention. For example, Zaffaroni et al. fails to teach a polymeric carrier region which is a *drug carrier* for the therapeutic agent and which *releases* the therapeutic agent. Rather, Zaffaroni et al. teaches a reservoir 12 of a drug carrier medium 13

containing a drug 14 (col. 4, lines 27-29) that is surrounded by a separate polymeric membranous wall 11 (col. 4, lines 24-52). The wall 11, made of poly(dimethylsiloxanes) or silicone-carbonate copolymers or other material (col. 13, lines 13-39), acts as a barrier for the liquid drug carrier 12. Thus, the wall 11, itself, does not serve as a *carrier* for the drug's release but is a *barrier*. As explained by Zaffaroni et al.,

> [i]n operation, drug carrier 13 serves as a reservoir by supplying dissolved drug 14 to wall 11 as drug molecules move through the carrier to bathe the inner surface of wall 11. Drug 14 present at the drug carrier/wall interface dissolves in and migrates through wall11, ultimately reaching the outer surface of wall 11. As drug 14 leaves drug carrier 13, undissolved drug present in reservoir 21 dissolves in carrier 13 to maintain a constant supply of dissolved drug in the carrier for continuously supplying drug at substantially the same rate to wall 11. (col. 4, lines 37-47)

> The permeability of wall 11 to the diffusion of drug 14 is lower than the permeability of liquid drug carrier 13 to the diffusion of drug 14 and passage through wall 11 thus acts as the rate limiting step for drug release from the device 10. (col. 5, lines 8-13).

Zaffaroni et al. stresses repeatedly that the drug carrier 13 and the wall 11 *are chemically and structurally distinct elements*. "In construction, the device can be viewed as a single unit constructed device comprising *two structures acting in concert for effective drug administration to a host*. One structure pertains to a wall comprising the device and formed of a drug release rate controlling material permeable to the passage of drug and the other structure relates to a reservoir comprising a drug carrier phase formed of a material permeable to the passage of drug. The materials forming the wall and the drug carrier phase comprising the device are *chemically and structurally different within a single device and the rate of release of drug through the wall is lower than the rate of passage of drug in the drug carrier phase*." (col. 8, line 61 to col. 9, line 6; col. 9, lines 56-60; col. 11, lines 8-10)(emphasis added).

Also, Zaffaroni et al. fails to teach a polymeric carrier region comprising the claimed *silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units*. There is simply no disclosure of a carrier medium comprising the claimed *silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units*. The Examiner states that "Zaffaroni discloses a silicone-carbonate copolymer in column 13, lines 29-30, which anticipates applicant's claimed polymeric release region comprising a silicone copolymer."

However, upon review in detail of the passage that the Examiner cites, it is evident that the silicone-carbonate copolymer pertains *only* to the wall and does not pertain to the drug carrier medium. (*See* Col. 13, lines 13-14 which states that "Exemplary naturally occurring or synthetic materials suitable for fabricating *the wall* are drug rate release controlling materials such as poly(methylmethacrylate)...Example of other materials include silicone rubbers, especially the medical grade poly(dimethylsiloxanes), and silicone-carbonate copolymers.")(emphasis added).

Zaffaroni et al. does not disclose a siloxane material for the drug carrier 13. It discloses that the "drug carrier medium used for the purpose of the invention is a liquid" (col. 13, lines 3-4) and the "[c]arrier 13 is fabricated of a non-solidified material permeable to the passage of drug, but the rate of passage of drug is higher in it than is the rate of passage of drug through the wall." (col. 7, lines 10-14). Various examples of gels, sols, oils, and syrups are provided in Col. 12, lines 3-15.

Thus, Applicants state that it has demonstrated that Zaffaroni et al. is missing at least the following claim features: 1) a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient; and 2) a polymeric carrier region comprising a silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units.

Given the above teaching, Applicants respectfully submit that Zaffaroni et al. fails to anticipate the invention as claimed. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(b) as anticipated by Zaffaroni et al.

Rejection Under 35 U.S.C. §102(b) Under Bruck

Claims 1, 4, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bruck (U.S. Pat. No. 4,559,054). Specifically, the Examiner asserts that Bruck "disclos[es[all of the claimed subject matter" and refers to column 2, lines 24-45 of Bruck.

In response, Applicants respectfully traverse the rejections and their accompanying remarks. For a reference to anticipate a claim it must disclose each and every element of the

claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Like Zaffaroni et al., Bruck fails as an anticipatory reference because it does not teach all of the claimed features of Claim 1 of the invention. Specifically, Bruck fails to teach a polymeric *carrier region that comprises said therapeutic agent and which releases said therapeutic agent* upon administration to a patient, said polymeric *carrier* region comprising a *silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units*.

The Examiner asserts that Bruck "disclos[es[all of the claimed subject matter" and refers to column 2, lines 24-45 of Bruck. However, upon review in detail of the passage that the Examiner cites, it is evident that Bruck et al. does not anticipate the claimed invention, but rather, teaches a separate *outer polymeric membrane* that surrounds a reservoir containing a lipophilic drug ("reservoir containing the drug in a pharmaceutically acceptable carrier and a medically acceptable, outer polymeric membrane surrounding said reservoir" (col. 2, lines 34-37, and line 67). The membrane is made of a block copolymer of poly(ether-urethane) and poly(dimethylsiloxane) (col. 2, line 68 to col. 3, line 31) and is a barrier to the release of the drug contained in the reservoir. The membrane itself does not comprise the therapeutic agent and is not a polymer carrier but is a polymer barrier. The therapeutic drug is contained in the reservoir in a "pharmaceutically acceptable carrier" (col. 8, lines 33-34).

Thus, Bruck is missing at least the following claim features: 1) a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient; and 2) a polymeric carrier region comprising a silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units.

Given the above, Applicants respectfully submit that Bruck fails to anticipate the invention as claimed. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(b) as anticipated by Bruck.

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Rejection Under 35 U.S.C. §102(b) Under Lee

Claims 1, 9-19, and 21-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lee (U.S. Pat. No. 4,833,218). Specifically, the Examiner asserts that Lee discloses, in column 11, lines 35-37 that "copolymers are useful for forming membranes to control delivery of a drug from a reservoir. Regarding the claimed transition temperatures, the embodiments are considered to be inherent from the Lee disclosure in view that the identical preferred polymers are disclosed."

In response, Applicants respectfully traverse the rejections and their accompanying remarks. For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

There is no disclosure of the claimed polymeric *carrier region that comprises said therapeutic agent and which releases said therapeutic agent* upon administration to a patient, said polymeric *carrier* region comprising a *silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units*. Rather, as the Examiner herself indicates, Lee discloses "copolymers [] useful for forming *membranes*." Like Zaffaroni et al. and Bruck, Lee discloses a *membrane* that serves as a *barrier* layer. There is no teaching of a polymeric carrier region which is the carrier medium for the therapeutic agent. There is no teaching of a polymeric *carrier* region comprising a *silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units*.

The following is an excerpt of the passage of Lee cited by the Examiner to support her assertion that the invention is anticipated by Lee:

> After conducting appropriate safety and efficacy testing for the compositions selected, cured elastomers of the present invention may find use in applications involving contact with the human body such as for the controlled delivery of drugs by incorporating the drug into the compositions of the present invention and curing the mixture or by using a membrane of the cured elastomer to control delivery of the drug from the reservoir. Some of the elastomers were optically clear after hydration and can find use in applications where transparent elastomers are required such as coatings for glass or for fabric treatments. (col. 11, lines 29-40).

The cited passage is a non-enabled and general statement about the future potential for using the disclosed compositions for such varied uses as "controlled delivery of drugs," "coatings for glass" and "fabric treatments" and is by no means sufficiently enabled to be an anticipatory reference for the claimed invention. Indeed, the passage is prefaced with the disclaimer that such future use can be made "[a]fter conducting *appropriate safety and efficacy testing* for the compositions selected" and offers no guidance about how to make and to use the disclosed compositions to achieve controlled delivery of drugs.

Regarding the Examiner's assertion that "the embodiments are considered to be *inherent* from the Lee disclosure in view that the identical preferred polymers are disclosed," Applicants respectfully disagree and state that the Examiner has not met her burden for establishing inherency. Applicants state that the claimed embodiments are not inherent in light of the disclosures of Lee, which discloses very specific structures for water-absorbable elastomers in which polyether blocks pendant from a silicon atom present in the polydiorganosiloxane segment of the block copolymers of Lee are terminally capped with an aliphatically unsaturated radical for copolymerization with an substantially water-insoluble organic monomer to result in a copolymer wherein all of the hydrophilic polyether segments are tied into the copolymer network (col. 3, lines 23-32).

A holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one. The fact that a certain result or characteristic ***may*** occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted); MPEP 2112 IV.

Applicants states that inherency has not been established.

Given the above, Applicants respectfully submit that Lee fails to anticipate the invention as claimed. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(b) as anticipated by Lee.

Rejection Under 35 U.S.C. §103(a)

Claims 8 and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zaffaroni et al.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicants state that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As indicated above with respect to the anticipatory rejection over Zaffaroni et al., Zaffaroni et al. fails to teach all of the claimed features. No secondary references were cited by the Examiner in this obviousness rejection of claims 8 and 20 for removing the deficiencies of Zaffaroni et al. Thus, since the prior art reference fails to teach or suggest all the claimed features, Applicants state that the Examiner has not established a *prima facie* case of obviousness

For at least these reasons, Applicants respectfully submit that claims 8 and 20 are patentable over the cited references. Given the above remarks and the amendments to the claims, Applicant states that the Examiner's rejection under 35 U.S.C § 103(a) has been obviated and Applicant respectfully requests that the Examiner withdraw the rejections.

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CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

FEES

The Office is authorized to charge any fees required to deposit account number 50-1047.

Respectfully submitted,

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